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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,751	03/26/2004	David S. F. Young	2056.039	9077

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EXAMINER	
REDDIG, PETER J	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/810,751	YOUNG ET AL.	
	Examiner	Art Unit	
	Peter J. Reddig	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-40 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-28, drawn to a method for treating a patient suffering form a cancerous disease comprising: administering to said patient an anti-cancer antibody or fragment; said antibody being an isolated monoclonal antibody or antigen binding fragment thereof which binds to an antigenic moiety expressed by said cancerous tissue, said antigenic moiety characterized as being bound by an antibody having the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4890, classified in class 424, subclass 141.1.

II. Claims 29-32, drawn to a binding assay to determine a presence of cells which express an CD63 antigenic moiety which specifically binds to an isolated monoclonal antibody encoded by the clone deposited with the ATCC as PTA 4890, or an antigen binding fragment thereof, classified in class 435, subclass 7.21.

III. Claims 33-40, drawn to a method of extending survival by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said

mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby survival is extended, classified in class 424, subclass 141.1.

It is noted for Applicant's convenience that this is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to methods with different objectives which do not share, as a whole, a substantial feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature disclosed as being essential to utility of the invention, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02.

IV. Claims 33-40, drawn to a method of delaying disease progression by treating a human tumor in a mammal, wherein said tumor expresses an antigen which specifically binds to a monoclonal antibody or antigen binding fragment thereof which has the identifying characteristics of a monoclonal antibody encoded by a clone deposited with the ATCC as accession number PTA-4890 comprising administering to said mammal said monoclonal antibody in an amount effective to reduce said mammal's tumor burden, whereby disease progression is delayed, classified in class 424, subclass 141.1.

It is noted for Applicant's convenience that this is a requirement for the election of a Group for examination NOT a requirement for an election of species because although the claims are presented in Markush format, the claims are drawn to methods with different objectives which do not share, as a whole, a substantial feature disclosed as being essential to their utility. Thus, the analysis of the claims, for restriction purposes, is subject to the findings of the court wherein the court found that unity of invention exists where entities included within a Markush group share a substantial structural feature

disclosed as being essential to utility of the invention, In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Since the members of the group do not share a substantial structural feature disclosed as being essential to utility of the invention, the group as claimed fails the Harnisch test and the claims are not accorded Markush restriction practice because they do not meet the requirements to be accorded Markush practice under MPEE 803.02.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions of Groups I-IV are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j).

In the instant case, the methods are related in that they all use a monoclonal antibody encoded by a clone deposited with the ATCC as PTA-4890. The inventions of Groups I-IV are materially distinct methods that differ at least in objectives, method steps, response variables, and/or criteria for success.

The method of Group I is distinct in that it has the distinct objective of treating a patient suffering from a cancerous disease. The method of Group II is distinct in that it has the distinct objective of determining the presence of cells which express a CD63 antigenic moiety. The method of Group III is distinct in that it has the distinct objective of extending survival by treating a human tumor in a mammal. The method of Group IV is distinct in that it has the distinct objective of delaying disease progression by treating a human tumor in a mammal.

Furthermore, searching all of the inventions of Groups I-IV would invoke a burdensome search. Some of the inventions have been classified separately. Thus, each of these inventions

has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Although some of the inventions are classified similarly, classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search.

Because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

3. Species Elections for Group I

A. Claims 1, 12, and 23 are generic to the following disclosed patentably distinct species of antibody:

1) conjugated

2) not conjugated

If applicant elects species A1 then applicant must elect a species from B

B. Claims 1, 12, and 23 are generic to the following disclosed patentably distinct species of conjugates:

1) toxins

2) enzymes

3) radioactive compounds

4) hematogenous cells

C. Claims 1and 12 are generic to the following disclosed patentably distinct cytoxicity mediated by the antibody:

1) antibody dependent cellular toxicity

2) complement dependent cellular toxicity

3) catalyzing of the hydrolysis of cellular chemical bonds

4) producing an immune response against putative cancer antigens residing on tumor cells

5) targeting of cell membrane proteins to interfere with their function

6) production of a conformational change in a cellular protein effective to produce a signal to initiate cell-killing

D. Claim 23 is generic to the following disclosed patentably distinct species of tissue of tumor origin:

1) colon

2) ovarian

3) lung

4) prostate

5) breast

E. Claim 23 is generic to the following disclosed patentably distinct species of antibody:

1) murine

2) human

4. Species Elections for Group II

A. Claims 29 and 31are generic to the following disclosed patentably distinct species of tissue of tumor origin:

1) colon

2) ovarian

3) lung

4) prostate

5) breast

5. Species Elections for Groups III and IV

A. Claim 33 is generic to the following disclosed patentably distinct species of antibody:

1) conjugated

2) not conjugated

If applicant elects species A1 then applicant must elect a species from B

B. Claim 33 is generic to the following disclosed patentably distinct species of conjugates:

1) cytotoxic moiety

2) radioactive isotope

C. Claim 33 is generic to the following disclosed patentably distinct cytoxicity mediated by the antibody:

1) antibody activates complement

2) antibody mediates antibody dependent cellular cytotoxicity

E. Claim 23 is generic to the following disclosed patentably distinct species of antibody:

1) murine

2) human

6. In accordance with the decisions in *In re Harnisch*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984), restriction of a Markush group is proper where the compounds within the group either (1) do not share a common utility, or (2) do not share a substantial structural feature disclosed as being essential to that utility. In addition, a Markush group may encompass a plurality of independent and distinct inventions where two or more members are so unrelated and diverse that a prior art reference anticipating the claim with respect to one of the members would not render the other member(s) obvious under 35 USC 103. Since the decisions in *In re Weber*, 198 USPQ 328 (CCPA 1978) and *In re Hass*, 198 USPQ 334 (CCPA 1978), it is proper for the Office to refuse to examine that which applicants regard as their invention, if the subject matter in a claim lacks unity of invention, see MPEP 803.02.

The above species are independent or distinct because they comprise structurally distinct molecules and have different modes of operation and different effects. Further, each species would require different searches and the consideration of different patentability issues.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species from each of group A, B, C, D, and/or E for the elected Group even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Applicant is advised that the reply to this restriction requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

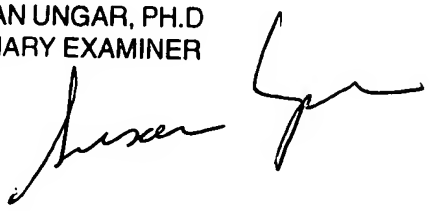
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter J. Reddig whose telephone number is (571) 272-9031. The examiner can normally be reached on M-F 8:30 a.m.-5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Peter J. Reddig, Ph.D.
Examiner
Art Unit 1642

SUSAN UNGAR, PH.D
PRIMARY EXAMINER



PJR